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Withdrawal of marketing authorisations for fenspiride medicines

EMA's safety committee (PRAC) has recommended that the marketing authorisations for fenspiride medicines be revoked, so the medicines can no longer be marketed in the EU. This follows a review that has confirmed that these cough medicines could cause heart rhythm problems.

The PRAC considered all the available evidence in its review. This included cases of QT prolongation and torsades de pointes (abnormalities of the heart's electrical activity that may lead to heart rhythm disturbances) in patients using these medicines, results of laboratory studies, data from published literature and stakeholder input.

Heart rhythm problems can be serious and occur suddenly, and it is not feasible to identify in advance the patients who may be at risk of these problems with fenspiride. In contrast, fenspiride medicines are used to treat non-serious cough. Therefore, the PRAC considered that these medicines should no longer be marketed.

The PRAC recommendation will now be sent to the CMDh¹ to make a decision about its implementation. The CMDh is a body representing EU Member States as well as Iceland, Liechtenstein and Norway.

Information for patients

- Cough medicines containing fenspiride will no longer be marketed in the EU because of data showing a risk of sudden, serious heart rhythm problems.
- You should stop taking these medicines and contact your doctor or pharmacist for advice on alternative treatments, if needed. You can check the ingredients of your medicine in the package leaflet accompanying the medicine.
- Patients are only at risk of heart rhythm problems with fenspiride while they are taking these medicines.
- If you have any concerns about your medicine, discuss them with your doctor or pharmacist.
- Return unused medicines to your pharmacy for appropriate disposal.

¹ Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human



Information for healthcare professionals

- Healthcare professionals should no longer prescribe fenspiride medicines and should advise their patients to stop taking fenspiride medicines.
- The withdrawal of the marketing authorisations of fenspiride medicines is based on case reports and nonclinical studies (including hERG channel binding) that showed that fenspiride can cause QT prolongation and has proarrhythmia potential (could cause triggering or worsening of arrhythmia) with the associated risk of torsades de pointes.
- Given the authorised uses of fenspiride for symptomatic treatment only and the seriousness of the safety concern, the benefit-risk balance of these medicines is negative for the currently authorised uses.

More about the medicines

Fenspiride medicines are available as syrup or tablets and used in adults and children from the age of 2 years to relieve cough resulting from lung diseases. In the EU, fenspiride medicines have been authorised via national procedures in Bulgaria, France, Latvia, Lithuania, Poland, Portugal and Romania and are available under various brand names (Elofen, Epistat, Eurefin, Eurespal, Fenspogal, Fosidal, Kudorp, Pneumorel, Pulneo, Еурспал and Сиресп).

More about the procedure

The review of fenspiride was initiated on 14 February 2019 at the request of France, under [Article 107i of Directive 2001/83/EC](#). At that time, the Pharmacovigilance Risk Assessment Committee (PRAC) recommended that supply of fenspiride medicines be suspended as a precautionary measure while the review was ongoing.

The review has been carried out by the PRAC, the Committee responsible for the evaluation of safety issues for human medicines, which has made its recommendation.

Because fenspiride medicines are all licensed at national level, the PRAC recommendation will now be sent to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) to make a decision about its implementation. The CMDh is responsible for ensuring harmonised safety standards for medicines authorised via national procedures across the EU, Iceland, Lichtenstein and Norway.